

REMARKS

Claims 9-12, 14-23, and 25-30 are pending in the present application.

The rejections of: (a) Claims 9-12, 14-23, and 25-30 under 35 U.S.C. §102(b) over: Baldacci, and (b) Claims 14-15 and 25-26 under 35 U.S.C. §103(a) over Baldacci in view of Noel, is obviated in part by amendment and traversed in part.

The presently claimed invention provides a method of (a) enhancing the production of nitric oxide in a subject in need thereof (see Claim 9 and claims dependent therefrom), or (b) enhancing the production nitric oxide synthase in a living body in a subject in need thereof (see Claim 20 and claims dependent therefrom), by administering to said subject in need thereof an effective amount of a composition comprising at least one compound selected from the group consisting of pyrrolidonecarboxylic acid, a pyrrolidonecarboxylic acid salt, and a pyrrolidonecarboxylic acid derivative, wherein said subject in need thereof is in need of a treatment selected from the group consisting of vasodilation, improvement of blood circulation, enhanced antiplatelet-aggregating activity, acceleration of absorption at the digestive tract, renal function regulation, neurotransmitting activity, promotion of erection, promotion of learning, and enhancement of appetite.

In the Office Action mailed February 9, 2006, the Examiner has taken the position that the disclosure of Baldacci inherently anticipates the claimed invention. This position is enunciated on page 3 of the Office Action mailed February 9, 2006, where the Examiner states "The examiner wishes to further elucidate the invention of Baldacci to further demonstrate that there is an overlapping patient population even over the claims as amended... The examiner respectfully points out that the currently amended claims include a treatment of antibacterial activity. As a patient in need thereof of treatment of antibacterial

activity, has an altered immune system, the immunomodulating activity of the compositions of Baldacci inherently anticipate the currently amended claimed limitation.” In response thereto, Claims 9 and 20 have been amended to remove “antibacterial activity.”

It is widely recognized that the discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using. *In re Hack* (MPEP §2112.02). This decision is consistent with the previously cited *Jansen v. Rexall Sundown Inc.* and supports the patentability of the subject matter of the present invention.

Notably, the only patients to whom the claimed compounds are administered in Baldacci (even when combined with Noel) are those in need of restoration of depressed immunodefenses. However, at no point do Baldacci or Noel, disclose or suggest a role for the claimed composition in the methods as presently claimed. Specifically, neither Baldacci, nor Noel, individually or combined, disclose or suggest the specific sub-set of subjects to which the composition is to be administered.

As previously noted, the U.S. Courts have recently held that a method of administering a compound "to a human in need thereof" is properly construed to require that the compound be administered to human with a recognized need to treat the recited disorder (*Jansen v. Rexall Sundown Inc.*, copy submitted with response filed April 28, 2005). To sufficiently distinguish the claimed methods on the basis of the subset of patients to be treated, Applicants have amended the claimed invention to define the subjects in need of enhanced nitric oxide production (Claim 9) or enhanced nitric oxide synthase production (Claim 20) based on the list of patient types appearing in Claims 9 and 20, which include the following:

“...wherein said subject in need thereof is in need of a treatment selected from the group consisting of vasodilation, improvement of blood

circulation, enhanced antiplatelet-aggregating activity, acceleration of absorption at the digestive tract, renal function regulation, neurotransmitting activity, promotion of erection, promotion of learning, and enhancement of appetite.”

The Examiner alleges “the compositions of Baldacci are clearly intended for the treatment of all pathologies resulting in altered immunodefenses.” However, beyond no evidence is provided in Baldacci, Noel, the Office Action mailed February 9, 2006, or in the art of record of what these pathologies would be. Further, there is nothing of record to suggest administering composition within the scope of the present claims to a patient as defined therein.

Therefore, as in *Jansen*, the claims of the present invention are drawn to administering a specific composition “to a subject in need” of either enhancing the production of nitric oxide or enhancing the production nitric oxide synthase, wherein the specific patient subset is defined. Therefore, the failure of Baldacci and Noel to disclose or suggest administering a composition within the scope of the present claims to a patient falling within the defined classes of patients with a recognized need to enhance the production of nitric oxide or enhance the production nitric oxide synthase would make the present invention novel and unobvious in view thereof. Applicants note that the foregoing is also consistent with *In re Hack*.

Applicants request withdrawal of these grounds of rejection.

Application No. 10/800,657
Reply to Office Action of February 9, 2006

Applicants submit that the present application is now in condition for allowance.

Early notification of such action is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.



Stephen G. Baxter
Attorney of Record
Registration No. 32,884

Vincent K. Shier, Ph.D.
Registration No. 50,552

Customer Number

22850

Tel: (703) 413-3000
Fax: (703) 413-2220
(OSMMN 08/03)